Amendments to the Drawings:

The attached Annotated sheets of drawings includes changes to Fig. 5 and Fig. 9 and replaces the original sheets including Fig. 5 and Fig. 9.

In Figure 5, the numeric reference label "34" has been changed to read as"30."

In Figure 9, the numeric reference label "64" has been changed to read as "58."

In Figure 9, the numeric reference label "58" has been changed to read as "64."

Attachments following last page of this Amendment:

Annotated Sheet Showing Change(s) (2 pages)

REMARKS

Reconsideration of the rejections set forth in the office action dated June 29, 2004, is respectfully requested. Applicants have canceled claims 26 and 31 without prejudice, and have added new claims 54-59. The new claims are fully supported in the specification, and no new matter has been added by way of this amendment.

Drawings

Figure 5 is objected to because of a mislabeled reference character for the "frame" of the fluid flow control device. This error has been corrected such that the reference character now reads as "30." A proposed drawing correction is provided.

Figure 9 is objected to because the "passage" of the fluid flow control device was labeled with two different reference characters in the specification. This error has been corrected such that the reference label "64" now reads as "58" and the reference label "58" now reads as "64" which corresponds to the amendments made in the specification. A proposed drawing correction is provided.

Specification

The specification is amended to correct the reference labels for Figure 9. On page 8, line 19, the reference label "64" has been inserted to describe the "slits" depicted in Figure 9, which is amended. Similarly, on page 8, line 21, the reference label "64" has been changed to read as "58" to be consistent with the reference label for the "passage" as described in Figure 9.

Rejection of Claim 33 Under 35 U.S.C. Section 112

The Examiner rejected claim 33 under 35 U.S.C. Section 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse this rejection for the reasons described below. (Applicants respectfully submit that the Examiner intended to reject claim 32 rather than claim 33. It is claim 32 that recites a resilient seal that seals against a pulmonic passageway during pulmonic placement and not claim 33.)

Applicants disagree with the Examiner's assessment of claims 25 and 32. According to the Examiner, claim 25 requires that the resilient seal form a seal with

the wall of the pulmonic passageway *after* device placement. Applicants respectfully argue, however, that there is no such limitation as to timing of the seal either expressed or implied within claim 25. Therefore, claim 32 provides an entirely appropriate limitation as to the timing of the sealing action not found within claim 25. Therefore, applicants respectfully request that the Examiner withdraw the section 112 rejection of claim 32.

Rejection of Claims 25-27, 31-33, 52 and 53 Under 35 U.S.C. Section 103

The Examiner rejected claims 25-27, 31-33, 52 and 53 under 35 U.S.C. Section 103 for allegedly being unpatentable over Leonhardt et al. (US 5957949) in view of Andersen et al. (US 5411552) and Lentz (US 5522881). Applicants respectfully traverse this rejection, as Leonhardt, Andersen, and Lentz, both alone and in combination, fail to teach the method of claim 25. For example, the cited references fail to teach placing in a pulmonic passageway a flow control device with a valve body that is biased into a closed configuration that restricts fluid flow through the valve body.

Leonhardt describes a valve stent 20 comprised of three elements, including a stent 26, a biological valve 22, and graft material 24. Leonhardt makes no mention of the biological valve 22 being biased into a closed configuration. To the contrary, since the valve 22 is a natural, biological valve, the valve 22 is passive in that it closes in response to a pressure differential across the valve, not in response to the valve being biased into a closed configuration. Although Leonhardt says that the valve 22 can be a mechanical valve, the teachings of Leonhardt dictate that such a mechanical valve would be a passive valve, not a valve that is biased into a closed configuration. One reason for this is that Leonhardt describes the valve's primary use as being for the replacement of the mitral valve. (See Figs. 2 and 9A-9D.) A natural mitral valve is not biased into a closed configuration. Rather, the mitral valve opens and closes entirely as a result of a pressure differential across the valve, not as a result of any bias in the valve. (See highlighted excerpts from Wikipedia, the Free Encyclopedia, http://en.wikipedia.org/wiki/Heart_valve, attached hereto as Appendix B.) Thus, Leonhardt actually teaches away from the valve 22 being biased

into a closed configuration, as such a valve would not properly emulate the mitral valve that it replaces.

Andersen also fails to describe a valve that is biased into a closed configuration. Andersen makes no mention of the valve being biased into a closed configuration. Like the valve in Leonhardt, the valve that is used in Andersen is a biological valve. Thus, the Andersen valve is a passive valve that closes in response to a pressure differential across the valve.

Lentz fails to describe any type of valve and, therefore, cannot provide the missing teachings. In view of the foregoing, applicants respectfully submit that the cited references fail to render obvious the method of claim 25. Claims 26-27, 32-33, and 52-53 are patentable on their own merits as well as based upon their dependency on claim 25. Accordingly, the rejections under 35 U.S.C. §103 should be withdrawn.

New Claim 54

New claim 54 recites that the pulmonic passageway comprises a lung passageway, and the resilient seal seals with a wall of the lung passageway so as to prevent fluid flow between the resilient seal and the wall of the lung passageway such that the flow control device allows fluid flow through the lung passageway when the valve body is in the open configuration and prevents fluid flow through the lung passageway when the valve body is in the closed configuration. None of the cited references describe placing a flow control device in a lung passageway. Indeed, none of the devices described in the cited references are suitable for use in a lung passageway.

For example, the Leonhardt device is unsuitable for placement in the lung as its construction provides several air leak paths that would prevent the device from preventing fluid flow through the lung passageway. The graft material that surrounds the Leonhardt valve stent is made of a porous material, which provides a source of leak paths. Although Leonhardt states that the graft material has a "low" porosity, any porosity at all will result in air leakage across the device if placed in a lung. Moreover, the Leonhardt valve stent includes sutures that are stitched between the graft and the frame to secure the graft to the frame. Such stitches create holes in

the graft that form additional leak paths through which air can flow across the device. Furthermore, Leonhardt teaches that the graft material is a "woven fabric". By definition, a woven fabric is formed of interweaved threads. Thus, a woven fabric inherently includes holes between the thread weaves in the fabric, which would result in additional leak paths across the device if it were placed in a bronchial sub-branch. Such leak paths would provide a passageway for air to flow across the Leonhardt device if it were positioned in a bronchial sub-branch.

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Applicants respectfully submit that the pending claims are now in condition for allowance and respectfully request the same. If the Examiner has any questions regarding the foregoing, he is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,

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Heart valve

From Wikipedia, the free encyclopedia.

In anatomy, the **heart valves** are valves in the heart that prevent blood from flowing the wrong way.

There are four valves of the heart:

- Two atrioventricular (AV) valves - ensure blood flows from the atria to the ventricles, and not the other way.
- Two semilunar valves - these are present in the arteries leaving the heart, and they prevent blood flowing back from the artery into the ventricle.

Heart valves open and shut depending on the difference in pressure on each side. The sound of the heart valves shutting causes the heart sounds.

Contents

AV valves

These are large, multicusped valves that prevent backflow from the ventricles into the atria during systole. They are anchored to the wall of the ventricle by chordae tendinae, that prevent the valve from inverting.

The chordae tendinae are attached to papillary muscles that cause tension to better hold the valve. Together, the papillary muscles and the chordae tendinae are known as the subvalvular apparatus. The function of the subvalvular apparatus is to keep the valves from prolapsing into the atria when they close. The subvalvular apparatus have no effect on the opening and closure of the valves, however. This is caused entirely by the pressure gradient across the valve.

Mitral valve

Also known as the *bicuspid valve*, the mitral valve gets its name from the resemblance to a bishop's mitre (a type of hat). It prevents blood flowing from the left ventricle into the left atrium. As it is on the left side of the heart, in must cope with a lot of strain and pressure, this is while it is made of only two cusps, as there is less to go wrong.

A common complication of rheumatic fever is thickening and stenosis of the mitral valve.

Tricuspid valve

The tricuspid valve is on the right side of the heart, between the right atrium and the right ventricle. Being the first valve after the venae cavae, and thus the whole venous system, it is the most common valve to be infected

(endocarditis) in IV drug users.

Semilunar valves

These are positioned on the pulmonary artery and the aorta. These valves to not have chordae tendinae, but are more similar to valves in veins.

Aortic valve

The aortic valve lies between the left ventricle and the aorta. The aortic valve has three cusps. During ventricular systole, pressure rises in the left ventricle. When the pressure in the left ventricle rises above the pressure in the aorta, the aortic valve opens, allowing blood to exit the left ventricle into the aorta. When ventricular systole ends, pressure in the left ventricle rapidly drops. When the pressure in the left ventricle decreases, the aortic pressure forces the aortic valve to close. The closure of the aortic valve contributes the A2 component of the second heart sound (S2).

The most common congenital abnormality of the heart is the bicuspid aortic valve. In this condition, instead of three cusps, the aortic valve has two cusps. This condition is often undiagnosed until the person develops calcific aortic stenosis. Aortic stenosis occurs in this condition usually in patients in their 40s or 50s, an average of 10 years earlier than in people with normal aortic valves.

Pulmonic valve

The pulmonic valve lies between the right ventricle and the pulmonary artery. Similar to the aortic valve, the pulmonic valve opens in ventricular systole, when the pressure in the right ventricle rises above the pressure in the pulmonary artery. At the end of ventricular systole, when the pressure in the right ventricle falls rapidly, the pressure in the pulmonary artery will close the pulmonic valve.

The closure of the pulmonic valve contributes the P2 component of the second heart sound (S2). The right heart is a low pressure system, so the P2 component of the second heart sound is usually softer than the A2 component of the second heart sound.

Pathology of the valves

- Endocarditis
- Stenosis - a constricture of the heart valve, making it hard for blood to get through.
- Insufficiency - the inability of the heart valve to close properly, meaning some blood can flow the wrong way.
- et cetera

Related topics

- Disorders of the valves
  - Aortic valve disorders:
    - Aortic insufficiency
    - Aortic stenosis
    - Aortic valve replacement
    - Aortic valve repair
    - Aortic valvuloplasty
  - Mitral valve disorders

        - Mitral valve prolapse
        - Mitral regurgitation
        - Mitral stenosis
        - Mitral valve replacement
        - Mitral valve repair
        - Mitral valvuloplasty
    - Pulmonic valve disorders
    - Tricuspid valve disorders
- Congenital heart disease
- Endocarditis
- Heart sounds

Cardiovascular system - Heart Edit (*http://en.wikipedia.org/w/wiki.phtml?title=MediaWiki:Heart&action=edit*)

Pericardium - Epicardium - Myocardium - Endocardium - Purkinje fibers - Cardiac pacemaker - Sinoatrial node - Atrioventricular node - **Heart valves**

Retrieved from "http://en.wikipedia.org/wiki/Heart_valve"

Categories: Cardiac anatomy